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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,020	01/12/2007	Lone Andersen	05198-P0016A	5593

24126 7590 07/08/2010

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EXAMINER	
LATHAM, SAEEDA MONEE	

ART UNIT	PAPER NUMBER
1782	

MAIL DATE	DELIVERY MODE
07/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,020	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Saeeda Latham	1782	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,22-24,32,33,35,37-44,56-63,65-67,71-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/29/2006, 7/26/2006, 11/16/2006, 1/23/2007, 4/3/2008, 8/4/2008, 9/2/2009
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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 72 and 73 provide for the use of at least one enzyme, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 72 and 73 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 4, 7, 8, 35, 44, 56, 60-62, 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Wildi et al., USPN 3751561.

5. Regarding claims 1, 61, 62, Wildi teaches oral hygiene composition comprising polymer enzyme products, the composition is stable, long-acting in use (abstract). The polymer-enzyme is much more stable by nature of the polymer-enzyme molecule and even greater improvement is seen with a plurality of enzymes attached to the same polymer molecule (column 4, lines 14-21). The polymer contains a free carboxyl or carboxylic anhydride groups to covalent bond with the enzyme (column 5, lines 31-34). Such polymers include EMA a polymer of ethylene and maleic anhydride (column 5, line 46).

6. Regarding claim 4, in one embodiment, the chewing gum composition contains polymer-enzyme products that includes gum base, glucose, sucrose [considered sweeteners], and flavor (see Example 3).

7. Regarding claims 7 and 8, copolymers may be used (column 12, line 2).

8. Regarding claim 35, in the absence of the teaching of water content in the gum, it is understood that the claim limitation is met.

9. Regarding claims 44, 56, the enzymes may be protease or carbohydrase such as dextranase [considered a transferase], levanase etc (column 7, line 32-35).

10. Regarding claim 60, in addition to the polymer-enzyme product, another protease or a carbohydrase may be present (column 7, lines 31-35).

11. Regarding claim 65, the optimal pH range is 5 to 9.5 (column 6, line 14).

12. **Claims 1, 4-6, 9-14, 24, 32, 33, 37, 56, 60, 61, 63, 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al., USPN 6773730.**

13. Regarding claims 1, 6, 9, 12-14, 32, 33, 61, Liu teaches ingestible and degradable gum bases and chewing gums including enzymatically hydrolyzed zein [considered biodegradable elastomer] (abstract). Enzymes used to hydrolyze the zein include proteases, endopeptidases, serine protease or thio proteases (column 4, lines 35-39).

14. Regarding claim 3, the sweeteners maybe coated (column 9, lines 46).

15. Regarding claim 4, the chewing gum base includes sweetener and flavor (column 2, lines 58-59).

16. Regarding claim 5, softeners are added (column 9, line 19). The gum may contain humectants, bitterness masking agents, ingestible materials, and emulsifiers [considered further additives] (column 8, lines 44, 54, 61; column 9, lines 2).

17. Regarding claim 10, the advantage is to provide improved elastomers for constructing chewing gum (column 3, lines 3-4).

18. Regarding claim 24, the molecular weight of zein is around 35,000 Daltons, after modification the hydrolysate is in the range of 3700 to about 5400 Daltons (column 4, lines 24-28).

19. Regarding claim 37, in the absence of the teaching of the filler, it is understood that the claim limitation is met.

20. Regarding claims 56, 60, 63, a variety of ingredients used with zein to construct the gum base include food grade microbial protease or plant protease extraction which contain thiol proteinases or serine proteinase or carboxyl proteinases or metalloproteinases, or combinations there of [considered more than one enzyme] such as trypsin, papain, collagenase (column 8, lines 35-43).

21. Regarding claim 71, the chewing gum is mixed and shaped into desired form such as rolling into sheets, extruded into chunks or casting pellets [considered compressed] (column 10, lines 12-14).

22. Claims 8, 12-14, 32, 33, 61 are considered product-by-process claims. The cited prior art teaches all of the positively recited composition of the claimed product. The determination of patentability is based upon the composition itself. The patentability of a product or apparatus does not depend on its method of production or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 22, 23, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wildi et al., USPN 3751561.

25. Claims 22 and 23 relate to the polymer having amorphous regions and being aliphatic. Wildi teaches oral hygiene composition comprising polymer enzyme products, the composition is stable, long-acting in used (abstract). The polymer-enzyme is much more stable by nature of the polymer-enzyme molecule and even greater improvement is seen with a plurality of enzymes attached to the same polymer molecule (column 4, lines 14-21). The polymer contains a free carboxyl or carboxylic anhydride groups to covalent bond with the enzyme (column 5, lines 31-34). Such polymers include EMA a polymer of ethylene and maleic anhydride (column 5, line 46).

26. Wildi does not teach amorphous regions or being aliphatic. Since these are considered properties of the polymer, it would have been obvious to one having ordinary skill in the art at the time of the invention to have polymerized the EMA of Wildi to have amorphous regions and be in an aliphatic structure based on the desired properties of the polymer-enzyme product of Wildi.

27. Claim 37 relates to filler. Wildi teaches oral hygiene composition comprising polymer enzyme products, the composition is stable, long-acting in used (abstract). The polymer-enzyme is much more stable by nature of the polymer-enzyme molecule and even greater improvement is seen with a plurality of enzymes attached to the same polymer molecule (column 4, lines 14-21). The polymer contains a free carboxyl or carboxylic anhydride groups to covalent bond with the enzyme (column 5, lines 31-34). Such polymers include EMA a polymer of ethylene and maleic anhydride (column 5, line 46). Wildi further teaches the gum base contains filler (See Example 3).

28. Wildi does not teach filler in the amount of 0 to 80 wt%. It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated filler and determined the conventional amount of filler employed in the chewing gum composition and have arrived at such amount depending on the texture of the final product.

29. **Claims 35, 38-44 and 56-59, 66, 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al., USPN 6773730.**

30. Claim 35 relates to the water content. Liu teaches ingestible and degradable gum bases and chewing gums including enzymatically hydrolyzed zein [considered biodegradable elastomer] (abstract). Enzymes used to hydrolyze the zein include proteases, endopeptidases, serine protease or thio proteases (column 4, lines 35-39). Liu further teaches the moisture absorption capacity of zein is less than 30%; one must balance the water retention ability and water solubility (column 3, lines 58-61).

31. Liu does not explicitly teach water content of less than 10wt%. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have selected less than 10wt% because of the overlapping range.

32. Claims 38-44 and 56-59, 66, 67 relates to the specific amount of enzyme, the specific types of enzymes, and molecular weight, optimum activity temperature and relative humidity. Liu teaches ingestible and degradable gum bases and chewing gums including enzymatically hydrolyzed zein [considered biodegradable elastomer] (abstract). Enzymes used to hydrolyze the zein include proteases, endopeptidases, serine protease or thio proteases (column 4, lines 35-39). Liu further teaches a variety of ingredients used with zein to construct the gum base include food grade microbial protease or plant protease extraction which contain thiol proteinases or serine proteinase or carboxyl proteinases or metalloproteinases, or combinations there of [considered more than one enzyme] such as trypsin, papain, collagenase (column 8, lines 35-43). Liu teaches one embodiment, wherein the zein has 0.2 % papain (Table 1).

33. Liu does not teach the specific amount of enzyme, the specific types of enzymes, and molecular weight, optimum activity temperature and relative humidity. Since these are considered properties of the enzymes, it would have been obvious to one having ordinary skill in the art at the time of the invention to have selected desired enzymes with desired properties and arrived at the proper enzymes and amounts needed to effectively increase the biodegradability of the chewing gum of Liu.

34. **Claim 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al., USPN 6773730 in view of Witzel et al., USPN 4301178.**

35. Claim 2 relates to a center filling. Liu teaches ingestible and degradable gum bases and chewing gums including enzymatically hydrolyzed zein [considered biodegradable elastomer] (abstract). Enzymes used to hydrolyze the zein include proteases, endopeptidases, serine protease or thio proteases (column 4, lines 35-39).

36. Liu does not teach a center filling. Witzel teaches liquid filled chewing gum that releases large amounts of liquid sweetener and/or flavor into the oral cavity (abstract). It would have been obvious to one having ordinary skill in the art at the time of the invention to have centered filled the gum liquid sweetener and/or flavor to have increased the organoleptic properties of the chewing gum of Liu to release flavor into the oral cavity.

37. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wildi et al., USPN 3751561 in view of Witzel et al., USPN 4301178.

38. Claims 2 and 3 relates to a center filling and coating, respectively. Wildi teaches oral hygiene composition comprising polymer enzyme products, the composition is stable, long-acting in used (abstract). The polymer-enzyme is much more stable by nature of the polymer-enzyme molecule and even greater improvement is seen with a plurality of enzymes attached to the same polymer molecule (column 4, lines 14-21). The polymer contains a free carboxyl or carboxylic anhydride groups to covalent bond with the enzyme (column 5, lines 31-34). Such polymers include EMA a polymer of ethylene and maleic anhydride (column 5, line 46).

39. Wildi does not teach a center filling and coating. Witzel teaches liquid filled chewing gum that releases large amounts of liquid sweetener and/or flavor into the oral cavity (abstract). After the chewing gum is cut, the pieces are dipped to make a moisture resistant coating of calcium alginate, and then coated with an insoluble moisture impervious coating such as confectioners glaze or shellac (see Example 1, column 6). It would have been obvious to one having ordinary skill in the art at the time of the invention to have centered filled the gum liquid sweetener and/or flavor and coated gum as taught by Witzel and increased the organoleptic properties of the chewing gum of Wildi to release flavor into the oral cavity and provide a moisture resistance.

Conclusion

40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saeeda Latham whose telephone number is 571-270-1154. The examiner can normally be reached on Monday to Thursday 8:00AM - 5:00PM EST.

41. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

42. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. L./
Examiner, Art Unit 1782

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1782